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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ER 1641/2900

Applicants : John O'Connor et al.  
Serial No. : 09/630,215  
Filed : August 1, 2000 Group Art Unit: 1641  
For : METHODS FOR PREDICTING PREGNANCY OUTCOME IN  
A SUBJECT BY hCG ASSAY

1185 Avenue of the Americas  
New York, New York 10036  
November 9, 2000

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the PTO-1449 form attached hereto as **Exhibit A**.

1. US Patent No. 4,514,505 issued April 30, 1985 to Canfield et al.;
2. US Patent No. 5,260,421 issued November 9, 1993 to Chappel et al.;
3. PCT International Application No. PCT/US99/02289, filed February 3, 1998, International Publication No. WO 99/41584, published August 19, 1999 on behalf of The Trustees of Columbia University in the City of New York;
4. Bogart et al., (1989) "Human Chorionic Gonadotropin Levels in Pregnancies with Aneuploid Fetuses", Prenat.Diagn. 9: 379-384;

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18. Birken et al., (1993) "Separation of Nicked Human Chorionic Gonadotropin (hCG), Intact hCG, and hCG Beta Fragment From Standard Reference Preparations and Raw Urine Samples", Endocrinology 133: 1390-1397;
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20. Birken et al., (1996) "Isolation and Characterization of Human Pituitary Chorionic Gonadotropin", Endocrinology 137: 1402-1411;
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41. O'Connor et al., (1988) "Development of Highly Sensitive Immunoassays to Measure Human Chorionic Gonadotropin, Its  $\beta$ -subunit, and Core Fragment in Urine: Application to Malignancies", Cancer Research 38: 1361-1366.

The subject application is a continuation of and claims the benefit under 35 U.S.C. §120 of PCT International Application No. PCT/US99/02289, filed February 3, 1999, which is a continuation-in-part of and claims the benefit under U.S.C. §120 of U.S. Serial No. 09/017,976, filed February 3, 1998.

The above listed references 18-30 were submitted to and considered by the United States Patent and Trademark Office in an Information Disclosure Statement filed on April 13, 1999, in connection with U.S. Serial No. 09/017,976, filed February 3, 1998. Above listed references 1, 2, and 37-41 were submitted to and considered by the United States Patent and Trademark Office in a Supplemental Information Disclosure Statement filed on August 18, 2000, in connection with U.S. Serial No. 09/017,976, filed February 3, 1998. Also, above listed references 3, and 31-36 are concurrently being submitted to the United States Patent and Trademark Office in a Supplemental Information Disclosure Statement filed on November 9, 2000, in connection with U.S. Serial No. 09/017,976, filed February 3, 1998. Above listed

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references 4-17 are concurrently being submitted to the United States Patent and Trademark Office in an Information Disclosure Statement filed on November 9, 2000, in connection with U.S. Serial No. 09/311,428, filed May 13, 1999. Accordingly, under 37 C.F.R. §1.98(d) copies of references 1-41 are not required to be provided to the United States Patent and Trademark Office, since they were previously submitted to or cited by the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120.

PCT International Application No. PCT/US99/02289, filed February 3, 1999, is a foreign counterpart application of the subject application. A Search Report was issued on September 13, 1999 in connection with PCT International Application No. PCT/US99/02289, filed February 3, 1999. A copy of the Search Report is attached hereto as **Exhibit B**. Above listed references 1, 2, and 37-41 were cited in the Search Report. As stated above, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously submitted to or cited by the United States Patent and Trademark Office in an application relied upon for an earlier filing date under 35 U.S.C. §120.

PCT International Application No. PCT/US00/13197, filed May 12, 2000, is a foreign counterpart application of the subject application. A Search Report was issued on August 11, 2000 in connection with PCT/US00/13197, filed May 12, 2000. A copy of the Search Report is attached hereto as **Exhibit C**. Above listed references 3, and 31-36 were cited in the Search Report. As stated above, under 37 C.F.R. §1.98(d) copies of these references are not required to be provided to the United States Patent and Trademark Office, since they were previously submitted to or cited by the United States Patent and Trademark Office in an

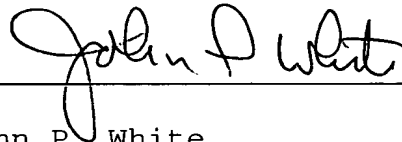
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application relied upon for an earlier filing date under 35 U.S.C. §120.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone at the number provided below.

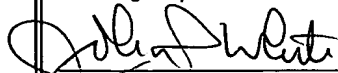
Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this paper is being deposited this date with the U.S. Postal Service as first class mail addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.



11/9/00

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